IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

The Cleveland Clinic Foundation, *et al.*	)	Case No.: 1:17-cv-00198-LMB-IDD
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
True Health Diagnostics LLC,	)	
	)	
Defendant.	)	

DEFENDANT TRUE HEALTH DIAGNOSTICS LLC'S
MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS

I. INTRODUCTION

Plaintiffs' Second Amended Complaint ("SAC") asserts three patents against True Health: U.S. Patent Nos. 9,575,065 (the "'065 patent"), 9,581,597 (the "'597 patent"), and 9,612,242 (the "'242 patent"). Each claim should be dismissed.

The '065 and '597 patents should be dismissed because both of these patents are invalid under 35 U.S.C. §101 for claiming patent-ineligible subject matter. The named inventors claim to have discovered a natural law that elevated levels of an enzyme—myeloperoxidase ("MPO")—correlate to an increased risk of having atherosclerotic cardiovascular disease ("CVD"). That correlation exists in nature apart from any human action. The '065 and '597 patents claim methods to observe this natural law using conventional, well-known techniques. But the Supreme Court and the Federal Circuit have made clear that claims merely reciting or observing a natural law using conventional techniques are invalid and subject to dismissal.

As for the '242 patent, Plaintiffs have not plausibly alleged infringement. The claims of the '242 patent require obtaining levels of both MPO and a second biomarker, F2-isoprostane, from the ***same bodily sample***, *i.e.*, blood, serum, plasma, or urine. To plausibly allege infringement, Plaintiffs must therefore allege that True Health tests at least one bodily sample for both MPO and F2-isoprostane. Because the SAC does not allege that True Health tests the same bodily sample(s) for both markers, the '242 patent should be dismissed.

I. THE '065 AND '597 PATENTS CLAIM A LAW OF NATURE AND ARE INVALID UNDER § 101

A. Background to the '065 and '597 Patents

The '065 and '597 patents generally relate "to the field of cardiovascular disease," and, more specifically, to diagnostic tests that "can be used to determine whether an individual . . . is

at a lower or higher risk of developing or having [atherosclerotic] cardiovascular disease than other individuals in a given population." *See* Dkt. 35-1, '065 patent, at 1:20-25.[1]

Cardiovascular disease is the number one killer in the United States. *See* Dkt. 35-1, '065 patent, at 1:32-34; *see also* Dkt. 23-1, SAC, at ¶ 15. CVD is a disease in which plaque builds up inside a person's arteries.[2] Over time, this plaque can harden and narrow the arteries, limiting blood flow and reducing the oxygen supply. Depending on where the plaque build-up or blockage occurs, CVD can lead to chest pain (angina pectoris), heart attack (myocardial infarction), and stroke. Dkt. 35-1, '065 patent, at 1:29-32.

At the time of the alleged invention, "several risk factors were used by members of the medical profession to assess an individual's risk of developing CVD and to identify individuals at high risk." *Id.* at 1:51-53. The major risk factors included cholesterol levels, hypertension, family history, smoking, and diabetes. *Id.* at 1:53-56. These risk factors "are additive, and are typically used together by physicians in a risk prediction algorithm to target those individuals who are most likely to benefit from treatment for CVD." *Id.* at 1:56-60. Nevertheless, "a large number of cardiovascular disorders occur in individuals with apparently low to moderate risk profiles." *Id.* at 1:66-2:1. For instance, "[w]hile cholesterol is the most common test used to identify CVD risk, approximately 50 percent of people who have had a heart attack previously displayed normal cholesterol levels." Dkt. 23-1, SAC, at ¶ 17.

[1] The '065 and '597 patents share the same specification, so, for convenience, True Health will cite only the '065 patent specification in the background sections.

[2] For the purposes of this Motion to Dismiss, the terms "cardiovascular disease," "CVD," and "atherosclerotic cardiovascular disease," mean the same thing.

1. The Named Inventors' Alleged Contribution to the Art was Discovering a Natural Law

The named inventors allegedly set out to develop a diagnostic test that is "easy to administer (like a cholesterol test) but that provides better predictive data of CVD risk." Dkt. 23-1, SAC, at ¶ 17; *see also* Dkt. 35-1. They explained that persons of ordinary skill in the art recognized that atherosclerosis was a chronic inflammatory disease of the arterial wall:

> Over the past decade ***a wealth of clinical, pathological, biochemical and genetic data*** support the notion that atherosclerosis is a chronic inflammatory disorder.

Dkt. 35-1, '065 patent, at 2:6-8 (emphasis added).

Given this evidence, by the time of the alleged invention, several groups of investigators had already begun looking for markers of inflammation in bloodstream to predict a patient's risk of developing or having CVD. For example, the Specification describes a previous clinical trial to evaluate if plasma levels of one such inflammatory marker, C-reactive protein, could independently predict the risk of first-time heart attack or stroke in apparently healthy individuals. Dkt. 35-1, '065 patent, at 2:12-18. The Specification also describes and incorporates an earlier patent—U.S. Patent No. 6,040,147—claiming methods to use C-reactive protein levels, among other things, to characterize an individual's risk of developing CVD. *See id.*; *see also* Ex. A, '147 patent, Claim 1.[3] Biomarker levels above the "norm" indicated a higher likelihood of CVD.

The named inventors did essentially the same thing as these other groups, but they focused on a different biomarker of inflammation: MPO. MPO is an enzyme released by white blood cells when inflammation occurs in the body. The named inventors did not discover MPO

[3] All exhibits are exhibits to the accompanying Oblon Declaration.

itself. Indeed, other investigators had already shown that MPO was involved in vascular inflammation and was present in atherosclerotic plaque, and suggested that there was a potential link between MPO and CVD. *See* Dkt. 35-1, '065 patent, at 6:66-7:1 ("Immuno-histochemical methods have demonstrated that MPO is present in human atherosclerotic lesions.").

Rather than discovering MPO itself, or first discovering the potential link between MPO and CVD, the named inventors simply hypothesized that individuals with higher levels of MPO in the bloodstream may have a higher prevalence of CVD. *See* Dkt. 35-1, '065 patent, at 7:1-3 ("MPO has not yet been shown to be present at increased levels in blood samples from individuals with atherosclerosis"). To test that hypothesis, they measured MPO levels (using conventional techniques) in patients with and without coronary artery disease. Based on those basic measurements, they allegedly "discovered" the naturally-occurring correlation between MPO in the bloodstream and the risk of having CVD. *See* Dkt. 35-1, '065 patent, at 2:36-40.

2. The '065 and '597 Patent Claims Merely Recite a Natural Law

The named inventors stated unequivocally that their alleged advancement over the prior art was the alleged discovery of a natural correlation:

> The ***present diagnostic tests are based on the discovery*** that patients with coronary artery disease (CAD) have significantly greater levels of leukocyte and blood myeloperoxidase (MPO) levels than patients without angiographically significant CAD.

Dkt. 35-1, '065 patent, at 2:36-40 (emphasis added).

The claims of the '065 and '597 patents merely confirm the natural law—that patients with CVD have elevated MPO levels in their bloodstream compared to non-diseased patients. Claim 1 of both the '065 and '597 patents, respectively, are shown below (with emphasis added):

> 1. A method of detecting ***elevated MPO mass*** in a patient sample comprising:

a) obtaining a plasma sample ***from a human patient having atherosclerotic cardiovascular disease (CVD)***; and

b) detecting elevated MPO mass in said plasma sample, as ***compared to*** a control MPO mass level from the ***general population or apparently healthy subjects***, by contacting said plasma sample with anti-MPO antibodies and detecting binding between MPO in said plasma sample and said anti-MPO antibodies.

* * * * *

1. A method for identifying an ***elevated myeloperoxidase (MPO) concentration*** in a plasma sample from a human subject with atherosclerotic cardiovascular disease comprising:

a) contacting a sample with an anti-MPO antibody, wherein said sample is a plasma sample ***from a human subject having atherosclerotic cardiovascular disease***;

b) spectrophotometrically detecting MPO levels in said plasma sample;

c) comparing said MPO levels in said plasma sample to a standard curve generated with known amounts of MPO to determine the MPO concentration in said sample; and

d) ***comparing*** said MPO concentration in said plasma sample from said human subject ***to a control*** MPO concentration ***from apparently healthy human subjects***, and identifying said MPO concentration in said plasma sample from said human subject as being elevated compared to said control MPO concentration.

The purpose of both claims is to detect elevated MPO in plasma samples from patients having CVD, *i.e.*, diseased patients. The fact that patients with CVD have elevated MPO levels in their bloodstream is the natural law that the named inventors allegedly discovered. Because both claims start with patients having CVD, "identifying" or "detecting" that their MPO levels would be elevated as compared to non-diseased subjects was a foregone conclusion, *i.e.*, a product of nature, based on human biology or physiology.

Thus, the '065 and '597 patents merely restate a natural law: patients having CVD have elevated MPO levels compared to the general population of apparently healthy subjects. And, as

explained more below, the laboratory techniques recited in the claims to detect elevated MPO levels were conventional.

3. The Northern District of Ohio Already Invalidated Nearly Identical Claims Reciting the Same Natural Law

This is the second lawsuit Plaintiffs have filed against True Health concerning the same alleged discovery. Plaintiffs previously sued True Health in their own backyard—the Northern District of Ohio—asserting that True Health infringed U.S. Patent No. 7,223,552 (the "'552 patent"), which is the "parent" patent of the '065 and '597 patents. This means the "child" '065 and '597 patents have the same Specification and rely on the same disclosure as the parent.

The now-invalidated parent '552 patent claims generally recite two basic steps: (1) "determining" MPO activity and/or mass in a patient's bloodstream; and, (2) "comparing" the patient's MPO levels to a predetermined control value. According to the patents' shared disclosure, "test subjects whose blood levels of MPO activity are higher than the predetermined value are at greater risk of developing or having [atherosclerotic] CVD than individuals whose blood MPO activity levels are at or lower than the predetermined value." Ex. B, '552 patent, at 2:59-63; Dkt. 35-1, '065 patent, at 2:62-66. For reference, claim 1 of the invalidated parent '552 patent states:

> 1. A method for characterizing a test subject's risk of having atherosclerotic cardiovascular disease, comprising:
>
> ***determining levels of myeloperoxidase (MPO)*** activity, myeloperoxidase (MPO) mass, or both in a bodily sample from the test subject, said bodily sample being blood, serum, ***plasma***, blood leukocytes selected from the group consisting of neutrophils and monocytes, or any combination thereof,
>
> wherein ***elevated levels*** of MPO activity or MPO mass or both in the bodily sample of the test subject ***as compared to at least one predetermined value*** based on levels of MPO activity, MPO mass or both, respectively, in comparable bodily samples obtained from control subjects diagnosed as not having the disease ***indicates that***

> ***the test subject is at risk of having atherosclerotic cardiovascular disease***.

Ex. B at Claim 1 (emphasis added).

The Ohio court dismissed Plaintiffs' complaint because, among other things, the parent '552 patent was invalid for claiming a natural law—***the same correlation between MPO levels and CVD***. The court concluded that the alleged invention claimed in the parent '552 patent was unpatentable as directed to a natural law:

> [T]he Court finds that the patents at issue are directed at a law of nature. Defendant claims that the patents recite the relationship between MPO levels in the bloodstream and the risk of having or developing CVD. Plaintiff does not respond to this argument. Upon review, the Court agrees with the defendant that the patents at issue are directed at a natural law, *i.e.*, the correlation between MPO in the blood and the risk of CVD.

Ex. C (2/23/2016 Order in *Cleveland Clinic Foundation, et al. v. True Health Diagnostics LLC*, No. 1:15-cv-2331 (N.D. Ohio)) at 10.[4]

The court held that determining MPO levels in blood, serum, plasma, and certain blood leukocytes was well-known and could be performed using well-known techniques:

> The '552 patent . . . contain[s] a "determining" step. That step, however, simply calls for determining the MPO mass or activity level from the blood [or plasma] sample by whatever method the user chooses. As defendant notes, a myriad of methods well-known in the art existed at the time of invention. The patents themselves acknowledge that such well-known techniques existed.

Id. at 11; *see also id.* at 2, n.3. The court further recognized that comparing MPO levels from a patient to a control group to determine if the levels were elevated was a mental process, and that the control samples described in the patent were derived from well-known techniques:

[4] Plaintiffs also asserted two other related patents—U.S. Patent Nos. 7,459,286 and 8,349,581, which were both also invalidated. They generally covered "[m]ethods for characterizing the near term risk of experiencing a major adverse cardiac event in a patient presenting with chest pain."

> Similarly, the "comparing" step is insufficient to satisfy the *Alice* test. As an initial matter, this step involves a mental process, which does not add an inventive step. This step simply requires comparing the MPO mass or activity level in the test subject to the level in a control population. The control samples are in turn derived from basic statistical techniques and can vary in form.

Id. at 11.

The only difference between this case and the Ohio case is that claim language has been shuffled, which is not enough to transform the claims of the '065 and '597 patents into a patent-eligible invention. *See Virginia Innovation Scis. Inc. v. Amazon.com, Inc.*, No. 1:16-cv-00861, 2017 WL 64147, at *5 (E.D. Va. Jan. 5, 2017) (commenting that courts "should endeavor to root out creative drafting efforts designed to monopolize the [natural law]" (internal quotation omitted)). The child '065 and '597 patent claims merely restate the same natural law using slightly different and reorganized words. With respect to the invalid parent '552 patent, the alleged invention covers: (1) determining MPO levels from a patient, (2) comparing those levels to a control group, (3) wherein elevated levels indicate the person is at risk of having CVD. With respect to the child '065 and '597 patents, the alleged invention covers: determining elevated MPO levels (as compared to a control group) from a patient having CVD. The few remaining limitations are, as discussed below, admittedly conventional techniques.

Plaintiffs also allege in this case that the named inventors "discovered a new and highly innovative method for 'seeing' MPO in the bloodstream. . . ." Dkt. 23-1, SAC, at ¶ 18. But Plaintiffs made the same argument in the Ohio case. Although Plaintiffs' assertion was and is

inaccurate,[5] the court accepted that assertion at the pleading stage but concluded nonetheless that detecting or "seeing" naturally-occurring values using known techniques was not patentable:

> According to plaintiff, it invented a specific way to "see" MPO. . . . [But] even though plaintiff may have been the first to "see" MPO by looking at the amount of MPO molecules and/or the enzymatic activity level, these values are naturally occurring and their discovery does not render the patents eligible under § 101.

Id. at 12-13. The court thus dismissed Plaintiffs' case, concluding that the parent '552 patent was invalid for failure to recite patent-eligible subject matter. *See* Ex. C at 18.[6]

B. Argument

1. Courts May Invalidate Claims under § 101 on the Pleadings

"Patent eligibility under 35 U.S.C. § 101 is an issue of law; as such, it is suitable for resolution on a motion to dismiss." *CalAmp Wireless Networks Corp. v. ORBCOMM, Inc.*, No. 3:16-cv-906-HEH, 2017 WL 536833, at *1 (E.D. Va. Feb. 9, 2017) (*citing Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1373 (Fed. Cir. 2016)). "The Court is permitted to make a patent eligibility determination at the Rule 12(b)(6) stage, so long as it has a full understanding of the basic character of the claimed subject matter." *Id.* (internal quotation omitted). Dismissing claims for lack of patent-eligible subject matter is especially appropriate where, as here, "there is no claim construction dispute relevant to the eligibility issue." *Genetic Techs.*, 818 F.3d at 1374. "As with all Rule 12(b)(6) motions, the Court's analysis is limited to the face of the complaint,

[5] *See, e.g.*, Ex. C at 12, n.6 ("Defendant argues that the prior art shows that, contrary to plaintiff's position, it was not the first to look at MPO mass in the blood. Defendant appears correct in this regard. The [Patent Office] rejected certain claims in the '552 patent as being anticipated by Minota, which 'teaches detecting MPO mass in blood from vasculitis patients.'").

[6] Plaintiffs have appealed that decision and that appeal is pending before the Federal Circuit. Oral argument was held on April 6, 2017.

materials incorporated into the complaint by reference, and matters of judicial notice." *CalAmp Wireless*, 2017 WL 536833 at *1 (internal quotation omitted).

2. Diagnostic Methods that Merely Recite or Observe a Law of Nature Are Not Eligible for Patent Protection

The patent laws do not "embrace[] every discovery." *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). Section 101 of the Patent Act sets out the threshold eligibility requirement. *See* 35 U.S.C. § 101. Although § 101 is written broadly, the Supreme Court has long held that it contains three important exceptions: laws of nature, natural phenomena, and abstract ideas are not eligible for patenting. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012) (citing *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

The Supreme Court has articulated a two-part test to determine whether claims recite patent-eligible subject matter. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l.*, 134 S. Ct. 2347, 2355 (2014). First, the court must determine "whether the claims at issue are directed to one of [the three] patent-ineligible concepts," *i.e.*, whether the claims are directed to a law of nature, natural phenomenon, or abstract idea. *Id.* If so, the court must determine whether the additional elements of the claims, individually and as an ordered combination, "'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo*, 132 S. Ct. at 1297-98). This second step searches for an "inventive concept"—"an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" *See id.* (quoting *Mayo*, 132 S. Ct. at 1294).

When evaluating the eligibility of diagnostic testing methods, like here, the primary question is "whether the claims do significantly more than simply describe" the natural law. *Mayo*, 132 S.Ct. 1297. Courts must distinguish between claims that merely "observ[e] or identify[] the ineligible concept itself," which are invalid, and claims that sufficiently transform a

natural law into a patent-eligible application, such as methods of "producing things" or "treating disease." *See Rapid Litig. Mgmt. Ltd. v. CellzDirect*, 827 F.3d 1042, 1048-49 (Fed. Cir. 2016). The Supreme Court has explained, "the first party with knowledge" of a natural law is "in an excellent position to claim ***applications of that knowledge***" rather than claim or recite the natural law itself. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 (2013) (emphasis added). Transforming and applying the discovery is the key; "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." *Id.* at 2117.

In *Mayo*, for example, the Supreme Court invalidated a diagnostic test method to optimize a drug's efficacy. The alleged invention identified links between certain metabolite concentrations in the blood and the likelihood that a dosage of a thiopurine drug would prove either ineffective or cause harm. *See id.* at 1296–97. Claim 1, for instance, recited ***administering*** a drug providing 6-thioguanine ("6–TG") to a subject, ***determining*** the level of 6–TG in the subject, ***wherein*** levels of 6–TG in the blood exceeding a certain amount indicated a need to decrease the dose. *See id.* at 1295. Before the invention, the scientific community did not know the precise correlations between metabolite levels and likely harm or ineffectiveness of certain doses. *See id.*

The Supreme Court held that the correlation between 6–TG blood levels and over/under thiopurine dosage was a patent-ineligible law of nature:

> The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

Id. at 1297. The Court further held that the "administering" step did not supply an inventive concept because it "simply refer[ed] to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs." *See id.* The "determining" step was similarly

insufficient to transform the claim into patent-eligible subject matter because it simply "[told] the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor . . . wishes to use." *Id.* As to the "wherein" clause, the Court found those clauses simply "[told] the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decision-making. . . ." *Id.* Finally, the Court addressed the combination of these steps and concluded that "to consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately." *Id.* at 1298.

In *PerkinElmer, Inc. v. Intema Ltd.*, 496 F. App'x 65, 66 (Fed. Cir. 2012), the Federal Circuit recognized that claims reciting the use of "[biological] markers from both the first and second trimesters of pregnancy to determine the risk [of fetal Down's syndrome]" were invalid under § 101. The claims required measuring specific biomarker levels and comparing the levels to a reference range (or control value) to determine the risk of fetal Down's syndrome. *See id.* The Federal Circuit explained that (1) "[n]o action beyond the comparison [was] required" by the claims, and (2) "the relationship between screening marker levels and the risk of fetal Down's syndrome" was a law of nature. *Id.* at 70. The "measuring" and "determining" steps were based on "known" techniques, as described in the specification, and merely told the user of the process "to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field." *Id.* at 71 (internal quotation omitted). Because the asserted claims recited an ineligible law of nature, "and no aspect of the method convert[ed]" the law of nature into a patentable application, "the claims [could not] stand." *Id.* at 73.

Conversely, in *CellzDirect*, the inventors discovered a natural law that certain liver cells (known as hepatocytes) could survive multiple freeze-thaw cycles. The inventors did not claim

the natural law itself, but instead, they claimed a particular ***application*** of their discovery: a method of preserving hepatocytes by taking previously frozen and thawed cells, separating viable cells from non-viable ones, and recovering and refreezing the viable cells. *See CellzDirect*, 827 F.3d at 1045. The Federal Circuit held that the claims were patent-eligible because they were not directed to merely observing this naturally-occurring feature, they covered a "new and useful laboratory technique" to preserve liver cells. *Id.* at 1048.

3. The '065 and '597 Patents are Invalid under 35 U.S.C. § 101

a. Step 1: The Claims are Directed to a Natural Law

Step 1 of the *Mayo/Alice* test looks at the "focus" and overall "character" of the claims. *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016). To understand the claims' "character as a whole," the claims must be "considered in light of the specification" to understand the "focus of the claimed advance over the prior art." *See Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016) (internal quotations and citations omitted). The focus of the '065 and '597 patent claims is on the unpatentable law of nature that patients with CVD have elevated MPO levels compared to non-diseased persons. This discovered correlation "exists in principle apart from any human action." *PerkinElmer*, 496 F. App'x at 70. The named inventors explained their discovery was the focus of the claimed advancement over the prior art:

> The ***present diagnostic tests are based on the discovery*** that patients with coronary artery disease (CAD) have significantly greater levels of leukocyte and blood myeloperoxidase (MPO) levels than patients without angiographically significant CAD.

Dkt. 35-1, '065 patent, at 2:36-40 (emphasis added); *see also Genetic Techs.*, 818 F.3d at 1375 (holding claims directed to ineligible subject matter where disclosure in specification noted "[t]he present invention is based on the discovery" of a natural law). Here, the named inventors'

advancement over the prior art was "newly discovered information about human biology," namely, that elevated MPO levels in the bloodstream correlate with having CVD. *See id.*

The Northern District of Ohio's opinion invalidating the parent '552 patent under § 101 is relevant. *See* Ex. C. The Ohio court evaluated the same specification disclosing the named inventors' same alleged advancement over the prior art and concluded that the parent '552 patent was "directed at a natural law, *i.e.*, the correlation between MPO in the blood and the risk of CVD." *Id.* at 10. While the claim language in the parent '552 patent is slightly different than the '065 and '597 patents, the focus of the claims is still the same alleged discovery and natural law. In *Esoterix Genetic Labs. LLC v. Qiagen Inc.*, No. 14-cv-13228, 2016 WL 4555613 (D. Mass. Aug. 31, 2016), for example, the court invalidated a parent patent on a motion to dismiss because it was directed to a natural law "describ[ing] the correlation between a naturally-occurring mutation in a cancer cell, and the likelihood that a particular type of known pharmaceutical compound will be effective in treating that type of cancer" and used well-known methods in the art. *Id.* at *3 (internal quotation omitted). The court later assessed child patents and explained that they shared "virtually identical specifications" and claimed similar natural correlations. *See id.* at *8. Importantly, the court held that "[a]lthough some of the claims in the [child patents] use slightly different language than the claims of the [invalid parent patent], or contain slightly different limitations, none of these variations provide a basis for distinguishing the claims from those of the [invalid parent patent], and [patentees] do not argue otherwise." *Id.* As in *Qiagen*, the child patents here are based on the same specification and are directed to the same natural correlation; the child patents are not meaningfully different from the invalid parent patent in terms of patent eligibility.

Finally, the fact that the claims recite steps of "obtaining" plasma samples, "detecting" elevated MPO levels, and "comparing" measured MPO levels to control values does not change the result. Those steps are not the named inventors' alleged advancement; they are simply steps necessary to observe the natural correlation. *See, e.g.*, *Mayo*, 132 S. Ct. at 1296-97 (claims held directed to a natural law even though they required determining the level of certain compounds in the blood and increasing or decreasing dosage based on whether that level was higher or lower than a target level); *Ariosa*, 788 F.3d at 1373-76 (claims held directed to natural law where focus of claimed advancement was discovery that paternally inherited traits appeared in maternal blood and claims did not recite any novel detection or amplification techniques).

The focus of these claims is on the natural correlation, not on any particular application of that correlation, such as a method to treat disease. The claims are therefore directed to patent-ineligible subject matter.

b. Step 2: The Claims Add No Inventive Concept

In Step 2 of the *Mayo/Alice* test, courts must "divorce the additional steps [of the claims] from the asserted natural phenomenon." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1286 (Fed. Cir. 2015) (Lourie, J., concurring in denial of *en banc* review). "A claim directed to a newly discovered law of nature . . . cannot rely on the novelty of that discovery for the inventive concept necessary for patent eligibility." *Genetic Techs.*, 818 F.3d at 1376; *see also Parker v. Flook*, 437 U.S. 584, 591-92 (1978) (explaining that in assessing patentability under § 101, the ineligible subject matter, like a natural law, is "treated as though it were a familiar part of the prior art").

The analysis is not whether the named inventors were the first to use conventional laboratory techniques to detect a natural law, *i.e.*, to detect that MPO levels are elevated in patients with CVD. "That argument implies that the inventive concept lies in the discovery" of a

natural law, which is improper. *Ariosa*, 788 F.3d at 1379; *see also Genetic Techs.*, 818 F.3d at 1378-79.

Rather, the test under Step 2 is whether the remaining elements of the claim, considered apart from the natural law, provide sufficient inventive concept to transform the law of nature "into a patent-eligible application." *Genetic Techs.*, 818 F.3d at 1376. "Claims directed to laws of nature are ineligible for patent protection when, apart from the natural laws themselves" they involve nothing more than "well-understood, routine, conventional activity previously engaged in by researchers in the field." *Id.* (citing *Mayo*, 132 S.Ct. at 1294) (internal quotations omitted).

(i) The '065 Patent Steps Were Well Known

Apart from the natural law, the '065 patent includes "well-understood, routine, conventional activity previously engaged in by researchers in the field." The claim recites:

> 1. A method of detecting elevated MPO mass in a patient sample comprising:
>
> a) obtaining a plasma sample from a human patient having atherosclerotic cardiovascular disease (CVD); and
>
> b) detecting elevated MPO mass in said plasma sample, as compared to a control MPO mass level from the general population or apparently healthy subjects, by contacting said plasma sample with anti-MPO antibodies and detecting binding between MPO in said plasma sample and said anti-MPO antibodies.

The "obtaining" step merely tells users to perform a routine task by any method they choose. *See Mayo*, 132 S. Ct. at 1297. The specification explains that "[w]hole blood is obtained from the individual or test subject using standard clinical procedures. Plasma is obtained from whole blood samples by centrifugation of anti-coagulated blood." Dkt. 35-1, '065 patent, at 6:31-34; Dkt. 35-5 at C0000136-137 (discussing prior art references Deby-Dupont and Faymonville); *see also* Dkt. 35-9 at C0000457.

The "detecting" step is likewise insufficient to render the claim patent-eligible. During prosecution, the Patent Office found that "it was well known in the art to detect MPO levels using antibodies directed against MPO" and cited numerous prior art references supporting such claim.[7] Dkt. 35-5 at C0000136. Applicants never challenged this assertion. Moreover, the specification admits that at the time of the alleged invention "[t]he mass of [MPO] in a given sample is readily determined by an immunological method, *e.g.*, ELISA" and "[c]ommercial kits for MPO quantification by ELISA are available." Dkt. 35-1, '065 patent, at 9:33-35. The named inventors never disclosed a novel method for detecting MPO mass nor did they claim one. To the contrary, they identified known methods for accomplishing the "detecting" step. *See id.* As the Patent Office found, detecting MPO levels using antibodies directed against MPO was a well-known technique at the time.

The combination of "obtaining" and "detecting" does not provide an inventive concept, either.[8] To start, one cannot "detect" a biomarker in a sample without first "obtaining" the sample. Moreover, the specification teaches that the combination of obtaining and detecting biomarkers, *e.g.*, C-reactive protein (Dkt. 35-1, '065 patent, at 2:12-18), was known in the art. *See also* Ex. A. Further, the claims in *PerkinElmer*, for example, disclosed the combination of "obtaining" and "detecting" biomarkers from both the first and second trimesters of pregnancy. 496 F. App'x at 66 (discussing claims from U.S. Patent No. 6,573,103, having a filing date of Apr. 29, 1999, that measure biomarker levels and compare those levels to a control group to assess risk). There is nothing inventive in the combination of the two claimed steps.

[7] The prosecution histories of the '065 and '597 patents are public records and are attached as exhibits to the SAC, so the Court can properly consider them.

[8] To the extent that Claim 1 of the '065 patent is read to include a "comparison" step, whether explicitly or inherently, that step is insufficient to supply the requisite inventive concept for the same reasons explained in the context of the '597 patent, below.

All that is left is the natural law that elevated levels of MPO in plasma correlate to an increased risk of having CVD. Once the natural law is recognized, the remaining steps, and the ordered combination of remaining steps, add no inventive concept.

(ii) The '597 Patent Steps were Well Known

The '597 patent claims also fail step two of the *Mayo/Alice* framework.

> 1. A method for identifying an elevated myeloperoxidase (MPO) concentration in a plasma sample from a human subject with atherosclerotic cardiovascular disease comprising:
>
> a) contacting a sample with an anti-MPO antibody, wherein said sample is a plasma sample from a human subject having atherosclerotic cardiovascular disease;
>
> b) spectrophotometrically detecting MPO levels in said plasma sample;
>
> c) comparing said MPO levels in said plasma sample to a standard curve generated with known amounts of MPO to determine the MPO concentration in said sample; and
>
> d) comparing said MPO concentration in said plasma sample from said human subject to a control MPO concentration from apparently healthy human subjects, and identifying said MPO concentration in said plasma sample from said human subject as being elevated compared to said control MPO concentration.
>
> 2. The method of claim 1, further comprising, prior to step a), centrifuging an anti-coagulated blood sample from said human subject to generate said plasma sample.

The first three steps simply describe well-known methods to determine the concentration of a biomarker in a patient sample. The fourth step includes a mental "comparison" step that is described in the specification as being based on routine statistical methods and is merely another step that captures the natural law that elevated MPO levels correlate with CVD.

The "contacting a sample with an anti-MPO antibody," "spectrophotometrically detecting," and "comparing . . . to determine the MPO concentration" steps (steps (a), (b), and (c) of claim 1, respectively) were well known in the prior art. During examination, the Patent Office

examiner explained that "it was well known in the art to detect MPO levels using antibodies directed against MPO or using spectroscopic methods" and cited numerous prior art references supporting that fact. Dkt. 35-9 at C0000455. The examiner further explained that "the generation of a standard of known MPO levels as well as a standard curve generated with known amounts of MPO to determine the MPO concentration of a sample is considered to be well-understood, routine, conventional activity already engaged in by the scientific community." *Id.* The applicants never disputed these points. Further, the specification explains that "[e]nzyme concentration was determined spectrophotometrically" and cited an article from 1970 to support the well-known technique. Dkt. 35-2, '597 patent, at 11:17-20.[9]

Step (d) of claim 1 also provides no inventive concept. It recites "comparing" the patient's MPO concentration to a control concentration from apparently healthy human subjects and then "identifying" the patient's MPO concentration as elevated compared to the control. "Comparing" and "identifying" simply tell users of the claimed method to perform a basic, routine task—the mere thought process or mental step of "comparing" a patient's test result to a control value and "identifying" the test result as elevated compared to the control. *See Ass'n for Molecular Pathology v. U.S.P.T.O.*, 689 F.3d 1303, 1334 (Fed. Cir. 2012) (holding that method claims "comparing" or "analyzing" two gene sequences to determine variances were unpatentable because they claimed only "abstract mental processes" of comparing two genetic sequences to determine if the two "are the same or different, wherein the later indicates an alteration. . . ."), *aff'd in part, rev'd in part on other grounds sub nom. Ass'n for Molecular*

[9] MPO is an enzyme secreted by white blood cells. The specification also cites prior art to describe how protein concentration can be determined using known methods. Dkt. 35-2, '597 patent, at 23:50-51. The specification describes MPO as "a tetrameric, heavily glycosylated, basic (PI.10) heme protein of approximately 150kDa." *Id.* at 6:48-50.

Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (not reviewing method claims). The patent does not teach or claim any new or novel way to make that comparison. *See* Dkt. 35-2, '597 patent, at 21:21-55. Indeed, the specification teaches that deriving the control value is routine: "[a]ppropriate ranges and [control populations] can be selected with ***no more than routine experimentation by those of ordinary skill in the art***." Dkt. 35-2, '597 patent, at 21:1-3 (emphasis added); *see also* Ex. C at 11 (finding that "comparing" involves a mental process, which does not add an inventive step, and that the same disclosure in the parent patent confirmed basic statistical techniques can be used to derive the control value).

The additional limitation found in dependent claim 2 adds only another routine technique: centrifuging an anti-coagulated blood sample to generate a plasma sample (a step that occurs prior to step (a) in claim 1). *See* Dkt. 35-2, '597 patent, at Claim 2. During prosecution, the examiner identified prior art disclosing this technique: "Deby-Dupont, as noted supra, teaches centrifuging the anti-coagulated blood sample to generate the plasma sample. . . . Faymonville teaches centrifuging the anti-coagulated blood sample to generate the plasma sample (see p. 310 under 'collection of samples' where samples of venous blood are subjected to heparin (anti-coagulant) and centrifuged)." Dkt. 35-9 at C0000457. The applicants did not challenge these findings. To the contrary, the named inventors described this additional step without suggesting it was new or anything other than routine. *See* Dkt. 35-2, '597 patent, at 6:31-34 ("Whole blood is obtained from the individual or test subject using standard clinical procedures. Plasma is obtained from whole blood samples by centrifugation of anti-coagulated blood.").

Finally, even when the steps of the claims are considered as an ordered combination, there is still nothing new or inventive. Other than step (d), all steps are routine techniques to measure MPO concentration. Step (d) is just an abstract mental process for comparing a

patient's MPO concentration to a control value (which the patent teaches can be derived using any number of well-known techniques). Taken together, the steps of measuring a biomarker and comparing the result to a control value were routine, and the specification teaches the same. Again, for example, the specification discusses performing the same combination of measuring a biomarker level and comparing to a control group, using the biomarker C-reactive protein. *See* Dkt. 35-1, '065 patent, at 2:12-18; *see also* Ex. A. As another example, the claims in *PerkinElmer* disclosed the combination of measuring biomarker levels from both the first and second trimesters of pregnancy, and then comparing those levels to a control to assess risk. 496 F. App'x at 66 (discussing claims from U.S. Patent No. 6,573,103, having a filing date of Apr. 29, 1999). There is nothing inventive in the combination of the claimed steps.

In sum, even assuming the named inventors discovered the natural law that elevated levels of MPO correspond to an increased risk of CVD (or stated another way, that patients with CVD have elevated MPO levels), there is nothing new or inventive in the claims that transforms them or recites significantly more. Like the parent '552 patent claims already held to be invalid, the claims here are also invalid. The claims are directed to patent-ineligible subject matter under § 101, and for similar reasons to the Northern District of Ohio, this Court should invalidate both child patents.

4. That the Claims Were Allowed Does Not Change the Analysis

In their SAC, Plaintiffs assert that the child '065 and '597 patents should somehow be treated differently because the Patent Office reviewed them under post-*Alice* law. *See, e.g.*, Dkt. 23-1, SAC, at ¶¶ 33, 36, 40, 42. But "[t]he standard is not clear and convincing for pre-*Alice* patents, [and] clearer and more convincing for post-*Alice* patents." *SkillSurvey, Inc. v. Checkster LLC*, 178 F. Supp. 3d 247, 255 n. 2 (E.D. Pa. 2016). The Patent Office's findings are not binding on this Court and "[t]he fact that the [asserted] patent was issued after *Alice* does not

affect the Court's analysis in any way." *Id.* (granting motion to dismiss, concluding asserted patent was invalid under § 101).

Plaintiffs fail to address the circumstances leading to issuance of the '065 and '597 patents. Two months ***after*** the Ohio court invalidated the parent patent claims, the Cleveland Clinic Foundation ("CCF") filed two expedited applications that later matured into the two child patents here. Dkt. 35-4 at C0000079; Dkt. 35-8 at C0000413. Despite having a duty to disclose to the Patent Office any information material to patentability (see 37 CFR § 1.56), CCF ***failed to disclose*** any documents or information from the first-filed Ohio case, including that the parent '552 patent (which is based on the exact same disclosure) had been invalidated by a district court for claiming a law of nature. That is, undeniably, information material to patentability. Yet CCF kept it from the Patent Office.

The examiner originally rejected the pending "child" claims under 35 U.S.C. § 101 for claiming an abstract idea (not for claiming a natural law). Dkt. 35-5 at C0000135; Dkt. 35-9 at C0000454.[10] In rejecting the proposed claims under § 101, the examiner noted that "it was well known in the art to detect MPO levels using antibodies directed against MPO or using spectroscopic methods" and cited numerous prior art references supporting such claim. Dkt. 35-9 at C0000455; *see also* Dkt. 35-5 at C0000136. As mentioned above, CCF never challenged

[10] In both applications, the examiner also issued a "double patenting" rejection against all proposed claims based on the parent patent claims (which unbeknownst to the examiner had recently been invalidated). *See* Dkt. 35-5 at C0000138-139; Dkt. 35-9 at C0000459-461. "A statutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the referenced claims(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s)." Dkt. 35-5 at C0000138-139; Dkt. 35-9 at C0000459. In other words, the examiner compared the parent patent claims to the proposed child patent claims and determined that the new claims, while not identical, were an obvious variation of the parent claims. To overcome the double patenting rejections, CCF filed disclaimers of any term beyond the term of the parent patent. Dkt. 35-6 at C0000207; Dkt. 35-10 at C0000562.

this assertion, but instead responded that "it is not well-understood, routine, or conventional to *identify elevated* MPO levels in *plasma* from a subject with *atherosclerotic* CVD." Dkt. 35-9 at C0000494; Dkt. 35-5 at C0000166 (emphasis in original). That statement, however, merely pointed out that the named inventors (supposedly) discovered the natural law.

The applicants did not claim to have invented a new technique for measuring MPO, nor did they purport to invent a new way to apply the natural law. CCF just rewrote the previously-invalidated claims: instead of starting with a patient and determining whether MPO levels are elevated to predict CVD, as in the invalid parent patent, the child patents start with a patient having CVD and confirm elevated MPO levels. CCF got the child '065 and '597 patents issued by withholding material information from the Patent Office: that prior claims based on the exact same disclosure were found invalid for claiming nothing more than a natural law. The examiner was not shown the analysis from the Ohio court invalidating the '552 parent patent and simply did not address the key issue here, which is whether the claims are ineligible based on the ***natural-law*** exception to § 101. To the extent the patent examiner allowed the claims on a theory that the discovery of the natural law was the non-conventional aspect of the alleged invention, such a determination is contrary to binding precedent, and this Court should reject it. *See Ariosa*, 809 F.3d at 1286; *Genetic Techs.*, 818 F.3d at 1376; *Flook*, 437 U.S. at 591-92.

The fact that the Patent Office withdrew its abstract idea rejection should not change this Court's analysis. *See also SkillSurvey*, 178 F. Supp. 3d at 255 n. 2 (E.D. Pa. 2016) ("The fact that the [asserted] patent was issued after *Alice* does not affect the Court's analysis in any way."). And, unlike the patent examiner, this Court has the benefit of complete information, including the analysis from a sister court invalidating the parent patent.

II. THE SECOND AMENDED COMPLAINT DOES NOT PLAUSIBLY ALLEGE THAT TRUE HEALTH INFRINGES THE '242 PATENT

Plaintiffs also allege that True Health infringes the '242 patent. While part of the same family, the '242 patent is different than the '065 and '597 patents because, among other things, the claims of the '242 require obtaining levels of both MPO and a second biomarker, F2-isoprostane, "in a bodily sample." Both MPO and F2-isoprostane are markers of inflammation.

The '242 patent includes three claims, which Plaintiffs assert (*see* Dkt. 23-1, SAC, at ¶¶ 45, 85). The three claims recite:

> 1. A method for ***detecting MPO*** activity and/or mass ***and F2-isoprostane levels*** comprising:
>
> a) providing:
>
> i) ***a first assay*** for determining the ***level of MPO*** activity and/or MPO mass ***in a bodily sample from a human subject***, wherein said first assay employs an anti-MPO antibody; and
>
> ii) ***a second assay*** for determining a level of an MPO-generated oxidation product ***from said bodily sample***, wherein said MPO-generated oxidation product comprises ***F2-isprostane*** (F2-iso); and
>
> b) performing said first and second assays to ***obtain*** an ***MPO*** activity and/or mass level ***and*** an ***F2-isoprostane level*** from said bodily sample, ***wherein said bodily sample is selected from plasma, serum, urine, or blood***.
>
> 2. The method of Claim 1, wherein said second assay employs a mass spectrometer.
>
> 3. The method of Claim 1, ***wherein said bodily sample is plasma***.

Accordingly, the claims of the '242 patent define four types of fluids or "bodily samples" to determine MPO and F2-isoprostane levels. In Claims 1 and 2, "said bodily sample is selected from plasma, serum, urine, or blood." In Claim 3, "said bodily sample" must be "plasma."

A. The SAC Does Not Allege that True Health Tests F2-isoprostane in a Relevant Bodily Sample

The SAC alleges that True Health tests plasma for MPO levels, *see* Dkt. 23-1 at ¶¶ 54-62, but never alleges that True Health tests plasma for F2-isoprostane. In fact, the SAC does not allege which bodily sample True Health tests for F2-isoprostane levels ***at all***. Plaintiffs make only a broad allegation (not even specific to F2-isoprostane) that "[o]n information and belief, True Health tests plasma, serum, urine or blood samples." *Id.* at ¶ 69. Even accepting the allegations of the SAC at true, Plaintiffs' claim is deficient. By failing to allege that True Health tests plasma, serum, urine or blood for F2-isoprostane, Plaintiffs have not plausibly alleged that Claims 1 or 2 are infringed. By failing to allege that True Health tests plasma for F2-isoprostane, Plaintiffs have not plausibly alleged that Claim 3 is infringed. The SAC therefore should be dismissed on this ground alone.

B. The SAC Must Plausibly Allege that True Health Tests the Same Bodily Sample(s) for MPO and F2-isoprostane to State a Claim

The parties initially addressed the '242 patent in the context of Plaintiffs' motion for leave to amend. There, Plaintiffs wrongly suggested that a claim construction dispute prevents this Court from ruling at the pleadings stage and dismissing Plaintiffs' claim. Not so.

When moving for leave to amend, Plaintiffs mischaracterized True Health's position and the core issue before this Court. Plaintiffs inaccurately suggested that True Health was trying to the limit the claims of the '242 patent to a "single" or "singular" bodily sample, such as single vial of blood:

> True Health's overly restrictive construction makes no sense because under its reading, one would not infringe the claims if the MPO test was performed on one vial of blood and the F2-isoprostane test was performed on a second vial of blood drawn from the same patient at essentially the same time.

Dkt. 31 at 17. To be clear, True Health is ***not*** arguing that the term "a bodily sample" means "a ***single*** sample of plasma, serum, urine or blood." Dkt. *Id.* at 15. (emphasis added). True Health is also ***not*** arguing that "a bodily sample" is, for example, "one vial of blood." *Id.* at 17. For the limited purpose of this motion, True Health will adopt Plaintiffs' construction that the article "a" as used in the phrase "in a bodily sample from a human subject" means more than one. *See id.* at 14. Even so, dismissal is warranted because True Health is moving on a different issue.

While not requiring the use of a ***singular*** bodily sample, the express language of the claims of the '242 patent requires that the ***same*** bodily sample is used to measure both MPO and F2-isoprostane—meaning that both biomarkers are measured in plasma, or urine, or blood, or serum.[11] For example, multiple vials of blood can be drawn from the same patient during a visit, with one vial used to test for MPO levels and a second vial used to test for F2-isoprostane levels. If blood is used to measure MPO levels then, to practice the claimed methods, blood must be used to measure F2-isoprostane. The claims do not cover mixing and matching bodily samples.

The issue before the Court turns on the use and meaning of the term "said" in the '242 patent claims. The claims of the '242 patent have three core limitations:

Step 1:	providing a first assay to determine MPO levels in "***a bodily sample from a human subject***"
Step 2:	providing a second assay to determine F2-isoprostane levels from "***said bodily sample***"
Step 3:	performing the first and second assays to obtain the MPO and F2-isoprostane levels from "***said bodily sample***"

The term "said" is not susceptible to multiple meanings; no claim construction is required. The term "said" is a patent law term of art that "refers to an earlier use of the [same] term in the

[11] A bodily sample is **not**, for instance, a vile of blood or a cup of urine; rather, blood is a bodily sample, urine is a bodily sample, plasma is a bodily sample, and serum is a bodily sample.

claim." *Intamin Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1333 (Fed. Cir. 2007). Here, the first step requires "a bodily sample" from a human subject. The second and third steps recite "said" bodily sample, which refers back to the "same" bodily sample(s) in the first step.

The Federal Circuit's opinion in *Creative Internet Advert. Corp. v. Yahoo!, Inc.*, 476 F. App'x 724 (Fed. Cir. 2011), is instructive because it addressed the same issue concerning the import of the term "said," which is now squarely before this Court. There, the claim required receiving "***an*** end user communication message," inserting a background reference into "***said*** end user communication message," and transmitting "***said*** end user communication message." *Id.* at 725-26. Though in a different procedural context, the parties in that case were arguing about the very same issue True Health raises here—*i.e.*, when a claim recites doing something to "a" subject (*e.g.*, receiving a communication message or testing a bodily sample for MPO) and later doing something else to "said" subject (*e.g.*, transmitting said communication message or testing said bodily sample for F2-isoprostane), whether both actions must be done on the "same" subject (*e.g.*, receiving and transmitting the same message or testing for MPO and F2-isoprostane in the same bodily sample):

> Creative told the jury "if the logic, the code in the computer program was capable of doing these three things, it infringes" without regard to whether all three elements operate on the same message. Yahoo! then urged the jury to find noninfringement based on the premise that all three elements [receiving, inserting, and transmitting] must operate on the same message.

Id. at 728. The Federal Circuit held that the claim in that case required that the "receiving," "inserting," and "transmitting" steps must operate on the ***same*** communication message because of the term "said," even while recognizing that the term "an end user communication message" was "broad enough to cover multiple messages." *Id.* Notably, the Federal Circuit relied on the patent law term of art, which does not require special claim construction:

> Creative's broader claim construction is incorrect. Although the antecedent phrase, "an end user communication message," is broad enough to cover multiple messages, each use of the phrase "said end user communication message" still refers to the antecedent phrase. . . . An infringing system must therefore contain logic configured to insert a background reference into the same messages that are received and transmitted by other logic in the program.

Id. Beyond *Creative*, the Federal Circuit and other district court cases have consistently held that a reference to "the" or "said" in a claim refers back to the ***same*** term, whether plural or not. *See Wi-Lan, Inc. v. Apple, Inc.*, 811 F.3d 455, 459 (Fed. Cir. 2016); *Rates Tech. Inc. v. Broadvox Holding Co., LLC*, 15 F. Supp. 3d 307, 333 (S.D.N.Y. 2014) ("Although RTI is correct that the antecedent phrase, 'a data transfer line' is broad enough to cover multiple lines, each use of the phrase 'the data transfer line' still refers to the antecedent phrase."); *Novartis Vaccines & Diagnostics, Inc. v. Wyeth & Wyeth Pharm., Inc.*, No. 2:08-cv-67, 2011 WL 3880552, at *2–3 (E.D. Tex. Sept. 2, 2011) (where claim recited "***a recombinant protein*** lacking all or a portion of the B domain of human Factor VIII" and later recited "***said recombinant protein*** consists of [a first and second amino acid sequence]," the claim required that "at least one recombinant protein lacking all or a portion of the B domain of human Factor VIII … must contain two and only two amino acid sequences"); *Netscape Commc'ns Corp. v. ValueClick, Inc.*, 684 F. Supp. 2d 678, 695 (E.D. Va. 2009).

As the Federal Circuit and numerous district court cases explain, the patent law term of art "said" refers back to the same term, even if the term is plural. Consequently, even accepting Plaintiffs' position that "a bodily sample" is broad enough to cover one or more bodily samples, practicing the method still requires testing the same bodily sample(s) that was tested for MPO, for F2-isoprostane. The SAC makes no such allegation and is therefore deficient.

III. CONCLUSION

True Health respectfully moves the Court to dismiss the SAC because, for the reasons discussed herein, the '065 and '597 patents are invalid and the SAC does not plausibly allege infringement of the '242 patent.

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CERTIFICATE OF SERVICE

I hereby certify that on the 5th day of May, 2017, a copy of the DEFENDANT TRUE HEALTH DIAGNOSTICS LLC'S MOTION TO DISMISS was served on all counsel of record via the Court's ECF system.

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